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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,005	10/24/2003	John W. Forsberg	1023-294USD1	9349
28863 7590 03/21/2008 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125				
EXAMINER FLORY, CHRISTOPHER A				
ART UNIT		PAPER NUMBER		
3762				
NOTIFICATION DATE		DELIVERY MODE		
03/21/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary

Application No.

10/693,005

Applicant(s)

FORSBERG ET AL.

Examiner

CHRISTOPHER A. FLORY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-21 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-21 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date 11/02/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2 November 2006 is being considered by the examiner. Based on this consideration, the finality of the Office Action of 3 May 2007 is withdrawn.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 2 November 2006 is insufficient. Reasons for this finding are provided in paragraph 4 below regarding the rejection of the claims under 35 U.S.C. §102(b) based on the provided Exhibits A-D.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12, 14-21 and 32 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention as evidenced by the §132 declaration and Exhibits A-D submitted by Applicant 2 November 2006.

Per Applicant's admission in paragraph 4 of the §132 Declaration, Medtronic, Inc. requested that Benchmark Electronics, Inc., i.e. an external and independent company, i.e. the "public," manufacture 222 programmers defined by the instant claims more than

one year prior to the earliest effective filing date of the instant application. Per paragraph 5, these programmers were manufactured by Benchmark Electronics, i.e. the "public," more than one year prior to the earliest effective filing date as well.

Regarding Exhibit A, it is noted that Medtronic's confidentiality is admittedly redacted; and substantial necessary information providing for a date of drafting of the shown figures or the personal involvement of one or all of the listed inventors of the instant application in the drafting and conceptualization process.

Exhibit C shows that only two testing batteries were performed on the subset of programmers used for experimental purposes. This lacks the necessary robustness to show diligence. Additionally, the redaction of an exact date on which the order with Benchmark Electronics was placed in each of the Exhibits makes it more difficult to estimate diligence, as an order date on 7 October 2002--the date of the first test--would be seen as a better potential showing of diligence than if the order had been placed at a substantially earlier date, e.g. 2001 or 2000.

Regarding Exhibits B and D, it is again noted that Medtronic's confidential information has been redacted. The extent to which experimental data (e.g. parameters, test values, test setup and procedure, and substantial results) has been omitted from Exhibits B and D forestalls determination that the provided Exhibits show any extent of rigorous scientific procedure and experimentation or successful results demonstrating significant and proven improvement over the art.

Further regarding Exhibits B and D (see paragraphs 6 and 7), It is noted that only 89 out of 222 programmers, or less than 50% of the available units provided by

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Benchmark Electronics, were used for experimental purposes. The rest are stated as being distributed to Medtronic employees for internal use. It is unclear what range of activities "internal use" could encompass, e.g. whether the controllers provided to employees might have been allowed to leave secure facilities or to what extent said employees might be allowed to discuss or disclose the nature of the device in a public setting.

Additionally, there is no evidence provided of a nondisclosure agreement on the parts of Medtronic, Inc. or Benchmark Electronics, Inc.

Thus, due to a lacking of evidence to the contrary, the contractual manufacture of 222 programmer units by the external, i.e. "public," company Benchmark Electronics, Inc. more than one year prior to the earliest effective filing date of the instant application is seen as a public use of the claimed invention, rejectable under 35 U.S.C. §102(b).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10, 11, 12, 14, 15, 17-21 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al. (US 6,516,227) in view of Whitehurst et al. (US 2003/0229383, hereinafter Whitehurst'383).

Regarding claims 1, 5, 19, 21 and 32, Meadows et al. discloses a medical device programmer for an implantable neurostimulator (TITLE; ABSTRACT; column 5, lines 25-35) comprising an IrDA infrared interface (Fig. 7D-2, IrDA module 640) to receive changes to software executed by a processor within the programmer (Fig. 7D, microprocessor 620) during an infrared communication session (column 39, lines 14-42); and a controller (UART circuit 644 and microprocessor 620) to activate the infrared communication session in response to power-up of the programmer (column 27, lines 38-54; column 31, lines 37-49; column 32, lines 35-36 and 50-62; column 36, lines 24-60; column 38, lines 18-21; column 38, line 33 through column 40, line 25).

Meadows et al. does not expressly disclose that the seeking period is finite and that the infrared interface is deactivated after a finite period of time if the communication session is not established. In the same field of endeavor, Whitehurst'383 teaches a sleep-listen cycle of seeking a communication session (Figs. 3A-C and related paragraphs) with an external programmer to allow the device to be placed in a low-power mode to minimize power consumption (paragraph [47]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with the finite period seeking session as taught by Whitehurst'383 to provide the Meadows et al. system with the same advantage of minimizing power consumption.

Additionally regarding the clause that the infrared communication session is initiated for a finite amount of time, Meadows et al. discloses that a telecommunicative link is established each time the patient or medical personnel change a stimulus

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parameter or initiate a charging session (column 17, lines 61-65), which means that each communication must necessarily terminate at some time before the next begins. Likewise, Meadows et al. discloses that the patient handheld programmer (HHP) is automatically turned off after a period of disuse, e.g. 1 minute (column 36, lines 50-53). Even if the unit were in constant IR communication with the external linking device, this automatic turning off of the HHP unit would also constitute the terminus of a finite infrared session. Therefore, this claim limitation does not distinguish the instant application over the prior art.

Additionally regarding the clause that the infrared communication session is initiated in response to power-up of the programmer, Meadows et al. discloses the following: that the clinician programmer is in telecommunicative contact with the HHP in a likewise fashion that the HHP is in communication with the implantable pulse generator (IPG) (column 17, lines 3-6); that the HHP communicates with the IPG in order to control the operating program and stimulation parameters, taken to be a "medical device program" (column 16, line 60 through column 17, line 13); that the IPG telemeters data to the HHP each time a communication link is established (column 17, lines 55-60) and on power-up (Fig. 4D; column 37, lines 7-11)); and further, that all programming systems used by the HHP and clinician's programmer are always appropriately synchronized so that any changes from one are reflected in the other (column 36, lines 24-28). Thus it is understood that the clinician programmer controls the operating program and stimulation parameters (i.e. "the medical device program") of the HHP in a likewise fashion that the HPP controls the operating functions of the IPG.

From this disclosure, one skilled in the art would further recognize that it is an inherent function of the Meadows et al. device that the infrared communication session is initiated on power-up of the HHP in order for the HPP and clinician programmer to be "always appropriately synchronized." Therefore, because communication initiation in response to power-up is understood to be an inherent property of the Meadows et al. apparatus, the instant application is not distinguished over the prior art in this regard. Alternatively, it would be obvious to start the IR seek session on power-up of the device since it is well-known in the art to provide power-up telemetry sessions in devices that have programmers to verify and/or update protocol and operational data within the system.

Regarding claims 3 and 4, Meadows et al. discloses that the software changes comprise changes to an operating system or changes to medical device programs (column 16, line 60 through column 17, line 13; column 36, lines 24-28).

Regarding claims 6 and 8, the device of Meadows et al. is shown in Fig. 5 to be constructed of a housing with more than one part (Fig. 5, column 36, line 46 discloses an upper housing). Any electronic device comprising housing of more than one part and containing software loaded on a memory inherently comprises a software loading port, where the port is considered to be the open portion of the housing in which the software-loaded circuitry is being inserted or affixed, and the other portion of the housing is considered to be the plate member covering the loading port.

Regarding claim 9, Meadows et al. discloses that the plate member be printed with identifying information (column 38, line 55 through column 39, line 15). Given the

configuration shown on the right side of the figure above, the disclosed labels on the buttons clearly satisfy this claim limitation.

Regarding claim 7, a JTAG interface is a well-known and inherent component of any electronic system using SRAM or EEPROM (Fig. 7D-2). Therefore, this claim limitation does not structurally distinguish the instant application over the prior art of Meadows et al.

Regarding claim 10, it is an inherent property of any functional electronic device using an operating system to contain software that includes instructions to implement that operating system. Therefore, this claim limitation does not distinguish over the prior art.

Regarding claim 17, Meadows et al. discloses an LCD display (Fig. 7D-1, LCD module 240; column 39, lines 15-42).

Regarding claims 2 and 20, the active time requirements of 5 to 10 seconds and less than or approximately equal to 10 seconds, respectively, are not limiting over the Meadows et al. device because Meadows et al. does not explicitly teach a system that shuts off its IR interface with a different time requirement. If the Meadows et al. system remains in use for an hour or is always on, then the IR interface is active for 5-10 seconds by nature of being on for longer than that. Likewise, if the patient or clinician using the device powers down after 8 seconds, then the IR interface has been active for 8 seconds, which satisfies the language of claims 2 and 20. Therefore, claims 2 and 20 do not patentably distinguish the instant application from the prior art. Alternatively, Whitehurst³⁸³ teaches a seeking time-out period of 10 seconds (paragraph [40]).

Regarding claims 11, 12, and 14, Meadows et al. discloses the invention substantially as claimed including a first and second circuit board (Fig. 7A, button pad 241 is disclosed as being on a separate printed circuit board; column 36, lines 44-49), but does not disclose expressly that the telemetry circuitry and antenna be on the first board and the display, display circuitry and control circuitry be on the second board. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with the two circuit boards as an obvious expedient to simplifying the manufacturing process and for the purpose of making the device of a size similar to other hand held devices that use a hinged two board design, such as cellular phones.

Therefore, it would have been obvious to modify the system/method of Meadows et al. to obtain the invention as specified in the claims, and the instant application does not patentably distinguish over the prior art.

Regarding claim 15, Meadows et al. discloses the invention substantially as claimed including that the device is small enough to hold comfortably in one hand powered by e.g. a single AA-sized battery in an internal battery compartment (column 38, line 55 through column 39, line 22), but does not expressly disclose that the battery bay extends at least partially into the internal antenna aperture. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. by extending the battery bay into the antenna aperture, because Applicant has not disclosed that such a positioning provides an advantage, is used for a particular purpose, or solves a stated

problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a battery compartment away from the antenna source or even an external power source since it appears to be an arbitrary design consideration that fails to patentably distinguish the instant application over Meadows et al.

Furthermore, having a battery bay that extends into an aperture defined by the antenna is almost inherent in the nature of a device small enough to be held in the hand (the figure provided above with a battery in place of the memory module provides a good example of this). Still further, the aperture as claimed could be defined as the housing of HHP 202, of which the battery bay is an inherently integral and internal part.

Therefore, it would have been an obvious matter of design choice to modify the system/method of Meadows et al. to obtain the invention as specified in claim 15, which fails to distinguish the instant application over the prior art.

Regarding claim 18, Meadows et al. discloses the invention substantially as claimed but does not disclose expressly that the infrared interface is positioned on a lower side surface of the housing. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. by positioning the infrared interface on a lower side surface of the housing, because Applicant has not disclosed that such a positioning provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an alternate placement of the IR interface since it appears to be an

arbitrary design consideration that fails to patentably distinguish the instant application over Meadows et al. Therefore, it would have been an obvious matter of design choice to modify the system/method of Meadows et al. to obtain the invention as specified in the claim.

6. Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al. in view of Whitehurst'383 as applied to claim 1 above, and further in view of Stanton et al. (US Patent 6,249,703).

Meadows et al. discloses the Applicant's invention substantially as claimed except for an external antenna. Stanton et al. teaches the use of an external antenna (Fig. 1, external antenna 28) with a patient programmer (10) to eliminate the need to place the programmer over the implant site during programming sessions, which is helpful for patients who cannot easily reach the implant site due either to physical condition or location of the implant site (column 6, lines 6-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with an external antenna for the same advantages taught by the Stanton et al. patent (motivation to combine provided by Stanton et al., column 6, lines 6-17).

Response to Arguments

7. Applicant's arguments with respect to claims 1-10, 11, 12, 14-21 and 32 have been considered but are moot in view of the new ground(s) of rejection.

Specifically regarding claim 1, Applicant argues that Meadows fails to disclose a controller to activate the infrared interface to seek an infrared communication session in response to power-up of the programmer. Since Meadows discloses multiple subsequent communication sessions, it is indeed inherent that not only is the duration of each session finite, but the duration of time between communications (i.e. the seeking period) is finite. Meadows also clearly sets forth that the external programmer interrogates (i.e. requests a communication session with) the implanted device to establish hardware recognition before beginning transmission of data and operational programs (column 27, lines 38-55). Meadows further discloses that hardware recognition (i.e. the initiation of an infrared interrogation session) is initiated as soon as the programmer is connected to the system, i.e. powered on (column 32, lines 35-36 and 50-62). What this tells us is that, at the request of the external programmer, the implanted device must inherently seek a communication session in order to establish an uplink for telemetering data to and from the external programmer. If there is no active seeking phase from the implanted device, no communication can ever be established between the two components. Again in column 38, lines 30-35, Meadows discloses that "once the hidden physician screen has been activated [i.e. powered on] a telemetered interrogation of the IPG is initiated."

Regarding claims 11, 12 and 14, Applicant argues that unsupported conjecture about design choice is not a proper basis for rejection. No unsupported conjecture was made in the Office Action. A two circuit board design is an obvious expedient to the design process. One needs look no further than the cell phones now carried by the

majority of Americans to see this. The folding design leaves a footprint half the size of the unfolded or one circuit board design and facilitates future repairs. It is also not new or novel, but rather an inherent physical property of insulative substrates between two circuitry components, e.g. air over a distance or placement on opposite sides of a non-conductive substrate such as a silicon-based circuit board, to reduce electromagnetic interference or noise between components. Less noise will arise between two components the further apart they are placed, albeit across an air gap or on two separate circuits. The Lee reference (US 6,614,664) was placed on the evidentiary record submitted with the original Office Action for the very reason of providing support for this established rejection.

Regarding claim 15, evidentiary record of a programmer comprising a battery bay extending at least partially into the antenna aperture can be found in Figure 25 of the Causey reference as well as in Figures 1A and 2B of Malek (US 2003/0177031), among others. It is again noted that one can look no further than a modern cell phone to realize that such a battery bay comprises obvious design choice. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2 November 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

27 March 2008

/George Manuel/
Primary Examiner